

A Post-market, Real-world Experience: Expanding Access to Care by Incorporating the Symani® Surgical System and Enabling Surgeons

NCT06725030

Status RECRUITING
Sponsor MMI (Medical Microinstruments, Inc.)
Enrollment 455 participants

Key Eligibility Criteria

Inclusion (13)

- At least 22 years of age
 - Patient agrees to participate in the study, return for all required follow-up visits, complete all study procedures, and has willingly provided written informed consent after receiving all information related to the study, its requirements, and the robotic assisted procedure
 - Patient has a clinical indication for a microsurgical anastomosis of vessels between 0.1 and 2.5 mm in conjunction with open free-flap surgery of the breast or extremities and/or lymphovenous anastomosis surgery of the extremities
 - Investigator deems the candidate acceptable for free flap transfer surgery and/or lymphovenous anastomosis surgery with a robotic assisted microsurgical anastomosis in accordance with the Symani System's Instructions for Use (IFU)
 - Free Tissue Transfer Surgery: N/A
- ... and 8 more (see full listing online)

Exclusion (28)

- Patients who are incapable and/or unwilling to provide informed consent
 - Active systemic infection under treatment with intravenous antibiotics
 - Clinically significant cardiovascular, digestive, respiratory, endocrine, or central nervous system disorders, previous mental disorders, or other disorders that may significantly affect the data collection or the ability to comply with the protocol per the investigators discretion
 - Known history of significant bleeding, coagulopathy, or Von Willebrand's disease
 - Patients with implanted pacemaker
- ... and 23 more (see full listing online)

Locations (4 total)

Cedars Sinai Medical Center, Beverly Hills, California, United States
Yale New Haven Hospital, New Haven, Connecticut, United States
Tampa General Hospital, Tampa, Florida, United States
... and 1 more locations

<https://clinicaltrials.gov/study/NCT06725030>

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